

CLAIMS

1. A method for preparing a drug eluting medical device comprising the application to said device of a polymer having active functional groups capable of chemically
5 binding biological molecules, characterised in that said application takes place in a single step by means of cold plasma methods.

2. A method according to claim 1, in which said polymers are chosen from among polymers having amine groups,
10 carboxyl groups and sulphhydryl groups.

3. A method according to claim 2 in which the precursors of said polymers having amine groups are chosen from among allylamine, heptylamine, aliphatic amines and aromatic amines.

15 4. A method according to claim 2 in which the precursors of said polymers having carboxylic groups are chosen from between acrylic acid and methacrylic acid.

5. A method according to claim 2, in which the precursors of said polymers having sulphhydryl groups are chosen
20 from among volatile mercaptans.

6. A method according to any one of claims 1 to 5, in which said cold plasma methods comprise cold plasma produced under vacuum using discontinuous or continuous technology.

7. A method according to claim 6, in which said cold plasma under vacuum is generated at a pressure which may vary between 0.01 and 10 mbar, at a power of between 1 and 500 W and for a period of time of not more than 30 minutes.

8. A method according to any one of claims 1 to 5, in which said cold plasma methods consist in cold plasma produced at atmospheric pressure.

9. A method according to any one of claims 1 to 8 in which the precursor of said polymer is in the form of a gas.

10. A method according to any one of claims 1 to 8, in which the precursor of said polymer is in the form of a vapour.

11. A method according to any one of claims 1 to 10, in which said polymer is applied in the form of film with a thickness of between 0.01 and 10 microns.

12. A method according to any one of claims 1 to 11, also comprising before the application of said polymer having functional groups a step of applying at least one layer of a drug incorporated where appropriate in a polymer capable of eluting said drug.

13. A method according to claim 12, in which said drug is chosen from the group consisting in anti-inflammatory, anti-proliferative and anti-migratory drugs and

immunosuppressive agents.

14. A method according to claim 13, in which said drug is 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-phenyl]benzamide

5 methanesulphonate.

15. A method according to any one of claims 12 to 14, in which the drug eluting polymer is chosen from among hydrophobic hydrocarbons, polyamides, polyacrylates and polymethacrylates.

10 16. A method according to claim 15 in which said hydrophobic hydrocarbons are chosen from among polystyrene, polyethylene, polybutadiene and polyisoprene.

17. A method according to claim 15, in which said polymer
15 is chosen from among polyhydroxybutylmethacrylate, polyhydroxyethylmethacrylate, where appropriate in combination with polybutadiene.

18. A method according to any one of claims 12 to 17 in which said drug which may be incorporated in a drug
20 eluting polymer is applied by means of immersion in a suitable solution or deposited by spraying.

19. A method according to claim 18 in which said drug eluting polymer is deposited in the form of film with a thickness of between 0.5 and 20 microns.

25 20. A method according to any one of claims 12 to 19, in

which when said drug is an anti-inflammatory, it is present in quantities of between 0.001 mg and 10 mg per device.

21. A method according to any one of claims 12 to 19 , in
5 which when said drug is an anti-proliferative, it is present in quantities of between 0.0001 and 10 mg per device.

22. A method according to any one of claims 12 to 19, in
which when said drug has an anti-migratory action, it is
10 present in quantities of between 0.0001 mg and 10 mg per device.

23. A method according to any one of claims 12 to 19, in
which when the drug is an immunosuppressant, it is
present in quantities of between 0.0001 mg and 10 mg per
15 device.

24. A method according to any one of claims 12 to 19 in
which when said drug is 4-[(4-methyl-1-
piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-
pyrimidinyl]amino]-phenyl]benzamide methanesulphonate, it
20 is present in quantities of between 0.001 mg and 10 mg
per device.

25. A method according to any one of claims 1 to 24, also
comprising a step of depositing biological molecules on
the surface of said polymer having stable reactive
25 functional groups.

26. A method according to claim 25, in which said biological molecules are chosen from among anti-thrombotic substances and hyaluronic acid.

27. A method according to claim 26, in which said
5 biological molecules are heparin.

28. A method according to claim 26 or 27, in which said biological molecules are deposited by immersing the medical device in an aqueous solution containing said biological molecules in a concentration of 0.01% to 1% by
10 weight.

29. A method according to any one of claims 1 to 28, also comprising a preliminary step of cleaning/washing said medical device.

30. A method according to claim 29, in which said
15 preliminary cleaning/washing step is followed by a step of pretreatment of said medical device to promote adhesion of the drug incorporated where appropriate in an eluting polymer to this device.

31. A method according to any one of claims 1 to 30, also
20 comprising the application of further biodegradable polymer layers over said biological molecule layer.

32. A method according to any one of claims 1 to 31, comprising in succession the application of at least one first layer of 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-
25 methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]-

phenyl]benzamide methanesulphonate included where appropriate in a polymer to the surface of said medical device, the application by cold plasma of at least one second layer of polymer of allylamine, the bonding of
5 heparin to said at least one second layer and application of at least one third layer of biodegradable polymer onto said heparin.

33. A drug eluting medical device obtainable by means of the method according to any one of the preceding claims.

10 34. A medical device according to claim 33, comprising a device structure, at least one first layer covering the surface of said structure comprising a drug, at least one second layer covering said at least one first layer comprising a polymer having stable reactive functional
15 groups and a biological molecule layer bonded to said at least one second layer by means of chemical bonding with said functional groups, in which said at least one second layer of polymer is deposited on said at least one first layer by means of a cold plasma method.

20 35. A medical device according to claim 34, in which said drug is a drug as described in any one of claims 13 to 32.

36. A medical device according to any one of claims 34 or 35, in which said drug eluting polymer is a polymer as
25 described in any one of claims 16 to 18.

37. A medical device according to any one of claims 34 to 36, in which said polymer having stable reactive functional groups is one of the polymers described in any one of claims 2 to 5.

5 38. A medical device according to any one of claims 34 to 37, in which said biological molecule is any one of the molecules in claim 26.

39. A medical device according to any one of claims 34 to 37, said device being chosen from among vascular
10 devices, prostheses, probes, catheters, dental implants or similar.

40. A medical device according to claim 39, said device being a vascular stent.

41. The use of polymers having reactive functional groups
15 chosen from among the polymers described in any one of claims 2 to 5, for covering medical devices, preferably vascular stents, by means of cold plasma methods of deposition.